



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Washington, DC 20204

June 7, 1999

Jonathan W. Emord, Esq.
Emord & Associates, P.C.
1050 Seventeenth Street, NW
Suite 600
Washington, DC 20036

Dear Mr. Emord:

This letter acknowledges receipt on May 25, 1999 of the two health claim petitions entitled "Petition for Health Claim: Folic Acid, Vitamin B₆, and Vitamin B₁₂ Dietary Supplements and Vascular Disease" and "Petition for Health Claim: Saw Palmetto and Benign Prostatic Hyperplasia," submitted on behalf of Julian M. Whitaker, MD; Durk Pearson and Sandy Shaw; American Preventive Medical Association; and Pure Encapsulations, Inc., pursuant to section 403(r)(5)(D) of the Federal Food, Drug, and Cosmetic Act (FFDCA). On the same day, you also submitted a petition entitled "Petition for Health Claim: Psyllium Fiber Dietary Supplements and Coronary Heart Disease." However, because the petitioned claim is already authorized by regulation under 21 CFR §101.81 and may currently be used on the products and in the manner described in the petition, the agency has concluded there is no need for you to submit this petition. We are returning the original copy of the petition to you under separate cover.

With receipt of these materials, the 100-day period for review in consideration of filing has begun. For each of the two health claim petitions referenced above, we will notify you on or before September 1, 1999, of the agency's decision to file the petition for comprehensive review or to deny the petition.

We note that, in both of the health claim petitions referenced above, the required analytical data on the amount of the substance present in representative foods that would be candidates to bear the claim were not included (see 21 CFR §101.70(f)). Please submit this information, including the necessary information on the assay method if no Association of Official Analytical Chemists (AOAC) method is available, as soon as possible in order ensure that the petitions are complete.

With respect to your submission entitled "Petition for Health Claim: Psyllium Fiber Dietary Supplements and Coronary Heart Disease," as mentioned above, we are not acknowledging receipt of this document under 21 CFR §101.70(j) as a petition for a health claim. A health claim for soluble fiber from psyllium seed husk and reduced risk of coronary heart disease is already authorized under 21 CFR §101.81.

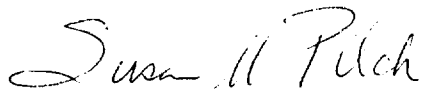
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ACK 1

This claim, as authorized, may be used for both conventional foods and dietary supplements. More specifically, in the general requirements for health claims, 21 CFR 101.14(a)(2), a substance is defined as, "a specific food or component of food regardless of whether the food is in conventional food form or a dietary supplement ..." When a substance that is the subject of a health claim can be provided by both conventional foods and dietary supplements, qualifying products of both types are eligible to bear the claim. Explicit mention is made of dietary supplements in current health claim regulations only when specific requirements exist, such as standards for assimilability or bioavailability or specific information needed for products containing very high levels of the subject substance, that pertain exclusively or mainly to products in the form of dietary supplements. In the case of psyllium, no such specific requirements exist, and the claim may be made now on both conventional foods and dietary supplements. It should be noted, however, that products in the form of dietary supplements that bear the claim and contain dry or incompletely hydrated psyllium husk, unlike products in the form of conventional foods, are not eligible for exemption from the requirement to bear a notice about the need to consume adequate fluid with the product (see 21 CFR §101.17(f)).

Please feel free to contact me at the above address or call me at 202-205-4500 if you have any questions.

Sincerely,

A handwritten signature in cursive script that reads "Susan M. Pilch".

Susan M. Pilch, Ph.D.
Team Leader, Nutrition, Health Claims
and Dietary Supplements
Office of Special Nutritionals
Center for Food Safety and Applied Nutrition